Public Health Committee Testimony – March 1, 2010
RB 5307: An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs

Good afternoon Representative Ritter, Senator Harris and the Public Health Committee. My name is Thomas Buckley, and I am an Assistant Clinical Professor of Pharmacy Practice at the University of Connecticut School of Pharmacy. I am here to speak in opposition of RB 5307: An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs. My rationale for opposition focuses on three main points:

(1) The legislation is unnecessary because Connecticut, like every other state, has generic substitution laws in place dictating that the prescriber already has the primary authority, at the time of writing the prescription, to indicate whether a generic substitution is permitted. Generic substitution is a well-established practice, and I have confidence in the current FDA system in which generic drugs are approved and evaluated. Any unnecessary mandate would inhibit access to prescription drugs that provide significant cost savings to consumers, health plans, and employers. Furthermore, adopting legislation that pertains to one type of medical problem, and the drugs developed to specifically treat it, encourages similar initiatives for other classes of medications, such as some that have already been proposed in other states for immunosuppressants and antiarrhythmic agents, and just last week here in the Insurance Committee for blood clotting drugs.

(2) Solutions exist for the difficult management of antiepileptic medications. The overall goal of antiepileptic medication is to completely prevent seizures and avoid side effects with a regimen that is convenient and easy to follow. People with epilepsy usually initiate treatment with one antiepileptic drug at the time of diagnosis, but 30% of patients will be refractory to this medication. While control of seizures is the over-riding goal of therapy, choosing an effective drug with the least potential for side effects becomes a crucial decision for clinicians. Although I agree that there are important challenges in treating patients with seizure disorders, I do not consider legislative changes necessary to address them. From a clinical management perspective, drug therapy protocols can be utilized through physician/pharmacist collaborative agreements to manage therapy closely and efficiently. From an economic perspective (while it may be beyond the purview of this committee), companies should lower their price to be competitive with generic formulations when patents of antiepileptic drugs expire. If the price is competitive, it removes the reason for which insurance companies or government agencies might expect the patient to be switched from brand to generic formulation. The reasons brand-name companies use in promoting legislative changes with respect to antiepileptic drugs focus on what they contend is an increased risk to patients of potentially serious consequences if their treatment is changed to generic formulations of the same medications. Treatments would not be changed if the drug became price-competitive unless it was medically necessary.

(3) My final point urges you to not pass legislation until we have evidence-based results to validate your decision. Fortunately, we will have that decision by the end of this December. The Agency for Healthcare Research and Quality (AHRQ) has granted a comparative effectiveness review of brand and generic antiepileptic medications. The organization that was given the grant by AHRQ to conduct this meta-analysis between February and December of 2010 is the University of Connecticut/Hartford Hospital Evidence-Based Practice Center, under the direction of my faculty colleague, Dr. Michael White. We are fortunate to have one of only 15 AHRQ evidence-based practice centers right here in Hartford, as results of these analyses drive health care decisions nationally utilizing an evidence-based approach to interpret existing research. AHRQ has just released the four key research issues on its website for the study titled "Evaluation of Effectiveness and Safety of Antiepileptic Medications in Patients with Epilepsy". They are open for public comment until March 11, and they include:

a. The comparative effectiveness of antiepileptic medications on 10 health outcomes

b. The comparative effectiveness of antiepileptic medications on intermediate outcomes such as pharmacokinetics and the comparative effective dose to control seizures

c. The comparative impact on serious adverse events

d. The comparative benefits or harm in subgroups of patients, such as different seizure types, age, gender, or ethnic differences.

As you can see, this will be the first and only exhaustive evidence-based research to be done in the comparison of antiepileptic medications, both between brand-name drugs and generic formulations. Since it will be completed and submitted to AHRQ for public release this December, I urge the committee that waiting until the release of this national guideline will help you make an informed decision the first time, and avoid unnecessary and costly legislation.